FDA 510(k) Premarket Notification

K992650 AIRIS, AIRIS II

CLEARED

Oct 8, 1999
63 days to decision

K992650 · Product code: **MOS** · Radiology
Source: https://www.510kdatabase.net/k992650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Aug 6, 1999
Decision date	Oct 8, 1999
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hitachi Medical Systems America, Inc.**
Location	Twinsburg, OH, US
Contact	JAMES JOCHEN ROGERS
510(k) history	100 submissions · 100 cleared · 1991-2017